NATIONAL ASSOCIATION OF ATTORNEYS GENERAL
750 FIRST STREET NE SUITE 1100
WASHINGTON, D.C. 20002
Phone - (202) 326-6015
Fax - (202) 408-7014
http://www.naag.org

LYNNE M. ROSS
Executive Director

October 28, 2003

By Courier
Hon. Tommy G. Thompson
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

By Mail
Thomas A. Scully, Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

By Courier
Thomas A. Scully, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: *Final Rule – 42 CFR § 447.534(h) and (i), Manufacturer Recordkeeping Requirements and Price Adjustments File Code CMS-2175-FC*

Dear Secretary Thompson and Administrator Scully:

We are writing to express our opposition to the implementation of CMS Final Rule 42 CFR § 447.534(h) and (i) (the "Rule"). This letter is intended also to serve as our comment on the Rule.

On August 29, 2003, the Centers for Medicare and Medicaid Services (CMS) published in the Federal Register (68 FR 51912) a Final Rule that makes two changes to the Medicaid Rebate program. First, it establishes a three-year limit within which a prescription drug manufacturer may submit drug pricing changes for purposes of the Medicaid Rebate program. Second, it entitles the manufacturer to destroy records concerning its pricing and price reporting practices after the same three-year period.

With regard to the three-year time limit on manufacturer price adjustments, we fully support the Rule. Three years is ample time for a manufacturer to calculate and report its average or lowest prices for a particular quarter, and it would constitute a substantial burden to require the states to issue rebate credits for unlimited periods of time. As to that portion of the Rule that permits a manufacturer to destroy records relating to its drug price calculation and reporting activities after only three years, however, we must voice our opposition in the strongest terms possible. As state Attorneys General, responsible for enforcement of the laws relating to fraud and abuse in the Medicaid programs, we cannot support any provision that would permit the destruction of potential evidence of fraud and thereby interfere with our effort to protect our taxpayers from fraud on our Medicaid programs.

Under the Rule, a manufacturer would be entitled to destroy records and data from which its average manufacturer price and best price were derived three years following the date that the manufacturer first reported the data to CMS. The Rule, were it to go into effect, would sanction the destruction of all records currently maintained by manufacturers reflecting the average manufacturer price and best price reports on products paid for by Medicaid agencies throughout the 1990s. The Rule would require a manufacturer to retain the earlier records only if it were "aware" of an unresolved "audit" or "government investigation" "related to average manufacturer price or best price."

At present, there are dozens of pending cases and investigations involving allegations of fraudulent pricing practices by prescription drug manufacturers, many of which look back well beyond the last three years. Lawsuits have been brought by the states of California, Connecticut, Florida, Kentucky, Massachusetts, Minnesota, Montana, Nevada, New York, Texas, and West Virginia alleging various improper data reporting practices from the 1990s to the present. In addition, many state Attorneys General and federal prosecutors are also engaged in ongoing confidential investigations of similar allegations of fraudulent pricing and violations of the Medicaid rebate statute and federal and state anti-kickback and false claims statutes. These investigations are, by necessity, conducted without notification to the manufacturers. Further, *qui tam* actions based on allegations of abusive pricing and marketing practices have been filed under seal throughout the country under state and federal false claims laws, and the preliminary investigation of such matters typically takes place without notice to the manufacturers. It is our responsibility to enforce the law with respect to these matters, and the destruction of documents concerning average manufacturer prices and best price rebates could interfere with our ability to meet our responsibility.

We understand that the development of the Rule is part of a larger effort to finalize the regulations under the Omnibus Budget Reconciliation Act of 1990. We also understand that the Rule is expected to streamline the Medicaid rebate process and reduce the attendant record keeping costs to our states' Medicaid programs. While these are worthy objectives, we do not believe they should be pursued at the risk of interfering with our efforts to investigate pricing fraud and to return public funds to our Medicaid programs. The recent resolution of criminal and civil best price violations involving drug manufacturers Bayer, GlaxoSmithKline and Pfizer have brought back nearly $400 million to federal and state treasuries. The results in these cases demonstrate the importance of protecting the integrity of our inquiries into the practices of prescription drug manufacturers.

This is not to say that no record retention rule would be acceptable. Most of the record retention programs under which prescription drug manufacturers operate in connection with their dealings with

Medicaid agencies require that records be maintained for six years following the transactions reflected in the records. We would be prepared to consider a rule that allows destruction of records by prescription drug manufacturers six years following the date the last best price adjustment for a particular drug quarter and particular product was submitted, with carve outs relating to records and data concerning matters under investigation. This approach would strike a more effective balance between efficiency and law enforcement concerns.

But the Rule, as currently written, could seriously interfere with the states' ability to investigate and prosecute the systematic fraud that is at the heart of pending cases, ongoing investigations, and *qui tam* filings. Accordingly, we urge you not to implement the provision in the Rule that would entitle prescription drug manufacturers to destroy records concerning average manufacturer price and best price reports.

Respectfully,

Attorney General Peter Heed
Attorney General of New Hampshire

Attorney General Tom Reilly
Attorney General of Massachusetts

Attorney General Gregg Renkes
Attorney General of Alaska

Attorney General Terry Goddard
Attorney General of Arizona

Attorney General Mike Beebe
Attorney General of Arkansas

Attorney General Bill Lockyer
Attorney General of California

Attorney General Ken Salazar
Attorney General of Colorado

Attorney General Richard Blumenthal
Attorney General of Connecticut

Attorney General M. Jane Brady
Attorney General of Delaware

Corporation Counsel Robert J. Spagnoletti
Corporation Counsel of D. C.

Attorney General Charlie Crist
Attorney General of Florida

Attorney General Thurbert E. Baker
Attorney General of Georgia

Attorney General Mark J. Bennett
Attorney General of Hawaii

Attorney General Lawrence Wasden
Attorney General of Idaho

Attorney General Lisa Madigan
Attorney General of Illinois

Attorney General Steve Carter
Attorney General of Indiana

Attorney General Tom Miller
Attorney General of Iowa

General A.B. "Ben" Chandler III
Attorney General of Kentucky

Attorney General Richard P. Ieyoub
Attorney General of Louisiana

Attorney General G. Steven Rowe
Attorney General of Maine

Attorney General J. Joseph Curran, Jr.
Attorney General of Maryland

Attorney General Michael A. Cox
Attorney General of Michigan

Attorney General Mike Moore
Attorney General of Mississippi

Attorney General Jeremiah W. Nixon
Attorney General of Missouri

Attorney General Mike McGrath
Attorney General of Montana

Attorney General Brian Sandoval
Attorney General of Nevada

Attorney General Patricia Madrid
Attorney General of New Mexico

Attorney General Eliot Spitzer
Attorney General of New York

Attorney General Roy Cooper
Attorney General of North Carolina

Attorney General Wayne Stenehjem
Attorney General of North Dakota

Attorney General Jim Petro
Attorney General of Ohio

Attorney General W. A. Drew Edmondson
Attorney General of Oklahoma

Attorney General Hardy Myers
Attorney General of Oregon

Attorney General D. Michael Fisher
Attorney General of Pennsylvania

Secretary of Justice Anabelle Rodriguez
Secretary of Justice of Puerto Rico

Attorney General Patrick Lynch
Attorney General of Rhode Island

Attorney General Henry McMaster
Attorney General of South Carolina

Attorney General Paul Summers
Attorney General of Tennessee

Attorney General Mark Shurtleff
Attorney General of Utah

Attorney General Greg Abbott
Attorney General of Texas

Attorney General William H. Sorrell
Attorney General of Vermont

Attorney General Jerry Kilgore
Attorney General of Virginia

Attorney General Christine Gregoire
Attorney General of Washington

Attorney General Darrell V. McGraw Jr.
Attorney General of West Virginia

Attorney General Peg Lautenschlager
Attorney General of Wisconsin

Attorney General Patrick Crank
Attorney General of Wyoming

cc: Centers for Medicare & Medicaid Services
Room 445 -- G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201